



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

[Docket No. FDA-2012-N-0002]

New Animal Drugs; Change of Sponsor's Name

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor's name from Novopharm Ltd. to Teva Canada Ltd.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Novopharm Ltd., 30 Novopharm Ct., Toronto, Ontario, Canada M1B 2K9 has informed FDA of a change of name to Teva Canada Ltd. Accordingly, the Agency is amending the regulations in 21 CFR 510.600(c) to reflect these changes.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

PART 510--NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. In §510.600, in the table in paragraph (c)(1), remove the entry for “Novopharm Ltd.” and alphabetically add a new entry for “Teva Canada Ltd.”; and in the table in paragraph (c)(2), revise the entry for “043806” to read as follows:

§510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Teva Canada Ltd., 30 Novopharm Ct., Toronto, Ontario, Canada M1B 2K9	043806
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
043806	Teva Canada Ltd., 30 Novopharm Ct., Toronto, Ontario, Canada M1B 2K9
* * * * *	

Dated: _ May 29, 2012.

Bernadette Dunham,

Director,
Center for Veterinary Medicine.

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